euro teknika GROUPE

MINI IMPLANT

obi

User's GUIDE

euroteknika groupe is the result of 20 years of clinical applications and 24 years of research and development confirmed by valuable help of international research laboratories.

The design of our implants is based on the skills of our teams wich are both reactive and experienced in implantology:

- Technical and biomechanical skills of our engineers enabling to guarantee the resistance of the component and their adaptation to the oral environment thanks to modern means of simulation.
- Biological and physiological skills of the associated laboratories enabling to validate the capacity of osseointegration of our systems.
- Clinical and practical skills of our dentists advisers ensuring the ergonomics of our products, the confirmation of our protocols and the ranges adapted to the various clinical cases.

The OBI type implant has 30 years of clinical experience. The first implants of this small size (< 3 mm) were placed in the USA in 1976. The Obi implant was inspired by numerous concepts from the evidence of the implants of larger diameter (asymmetrical thread, flared neck), it is a very usefull addition to your current system.

To enable you to take the best advantage of the OBI implant, we created this manual with a profesionnal care. We invite you to read it with your best attention. Each detail, even the least important, has its importance and underlines even more the difference between the beginner and the specialist.

Contents

Warning

The placement of **euroteknika groupe** implants must be done by a practioner who has been previously trained for the dental implantology techniques and in aseptic conditions specific to this type of treatment.

The following instructions will guide you throughout the different stages of your implantology treatments. They contain advice as precise as possible but cannot be used as «recipes», every clinical situation must be evaluated for each patient. A great number of factors acts independently to obtain success in an implantology treatment. It is up to the practioner to recognize the key factors and to use his clinical experience. Among other aspects, the coordination between the prosthesis laboratory dental technician and the practioner must be perfect so as to give the global treatment plan more consisting. Only the practioner remains responsible for his different choices and decisions as to the treatment's feasibility, implants, prosthetic parts, materials used and settings... The technical specifications and clinical advice in this manual are given solely as a guideline and cannot give rise to any claims. All the essential information is indicated in the instruction for use supplied with products.

We have taken great care in the design and production of our products. However, we reserve the right to bring modifications or improvements arising from new technical developments in our implantology system.We will advise of any modifications having an implication in the operation mode. According to the importance of the modifications, a new manual will be issued. Indeed, a mark on the back page indicates the date of issue of your surgery manual, and enables us to check if you have the latest up date version. You will also be able to access our web site to check the latest version of this manual.

GENERAL INFORMATION

IMPLANT **preferred usages**

- Lack of retention of a prosthesis
- Instability of a prosthesis
- Functional discomfort with the prosthesis
- Psychological refusal of the wearing of a prosthesis
- Parafunctional practices which compromise the stability of a prosthesis
- Inadequate localization and number of remaining abutments
- Lack of dental abutment to perform a fixed prosthesis
- Edentulous area with healthy adjacent teeth
- Request for a treatment preserving the adjacent healthy teeth
- Dental agenesis
- Request for a preservation treatment (reffusal of alteration of healthy teeth)

The Obi implant is a trans-muscous implant

Conceived to be placed in one surgical operation; its characteristics give it a greater primary stability so as to perform immediate loading when the practioner consider that all the necessary conditions for this sort of accelerated treatment are present.

Overdentures stabilization

On the narrow alveolar ridges, and patients unable to afford full sized root form implants, or prefer not to have several surgeries, 2 to 4 OBI implants enable to stabilize an overdenture.

Implantation optimization

Its small diameter and its reduced price allow to use it where a traditional implant is too voluminous (It is the case of central incisors), or to use it as a supplement to the classic implants to give more support to the prosthesis. Thanks to its burn-out abutment, it also allows to replace 2 roots of the same tooth (for molars for instance).

Temporary implant

Their small diameters allow the practitioner to place mini-implants between definitive implants within the same surgical time.
Whereas the latter will be buried, mini-implants will allow a provisory prosthesis to be seated, thus bringing an esthetic solution to the patient while respecting necessary time for osseointegration of main implants.

Narrow mesio-distal edentulous spaces

Replacement of a central lower incisor or of a lateral incisor*.

Contra indications FOR USE OF THE IMPLANTS (REMINDER)

Absolute contra indications

- Major psychological disorders
- Risky cardiopathy
- Uncontrolled systemic pathology
- Alcoholism or medicinal drugs addiction
- Age of the patient (young patient during growth)
- Poor hygiene of the patient

Relative contra indications

They are represented by:

- Insufficient volume and / or an osseous quality
- An insufficient restorative space
- A patient presenting risks (patient exposed to atomic radiation, bruxism, uncontrolled parodontitis, addiction to smoking)
- A D4 type bone for a single implant.

(*) The OBI implant cannot be used for the stabilization of a canine. For the replacement of a molar, it must be placed with a second OBI implant (or other).

Guarantee

In case of non osseointegration, you must inform your commercial representative so that we can examine the causes for the failure and bring the necessary corrective actions. An exchange may take place when the defect of the product is established; if the failure results from an incorrect clinical analysis, a surgical protocol not adapted to the case, from the use of blunt drills...or for any other reason independant from the product quality, the guarantee will not be taken into consideration.

Parts PACKAGING

Sterility and rule of asepty

- Most of our parts are delivered sterile and can therefore be used straightaway. A reference indicator shows the components effective sterility on the packaging. The sterility is guaranteed for 5 years (from packaging date). A standard expiry date is shown on the labelling.
- Only an undamaged packaging can guarantee the products imperviousness and sterility. Do not use implants with packaging which has been damaged or prematurely opened.
- Our products have been designed so as to enable handling without affecting their sterility. It is therefore important to follow a precise handling technique so as not to compromise the conventionnal hygiene conditions associated with the implant practice.
- The non sterile instruments and items delivered, used for the implantology treatment must be decontaminated and, according to a tested process, sterilized at the practice.

	Sterile	No sterile
Implants	x	
Prosthetic parts		x
Drills		x

Labels

Our implants are delivered with 2 labels showing clearly the mark, the reference and the lot number:

- 1 label for the patient's file of the practioner who placed the implant.
- 1 label for the correspondent if need be.

With this manual, some patients cards are included to be filled in with the references of the implants placed and to be handed to the patient. This enables any re-intervention on socket, wherever the patient lives.

Storage OF THE PRODUCTS

The implants must be stored in clean, dry and cool conditions.

Precautionary MEASURES

- It is strongly advised to keep in stock, implants which cover the most frequently used diameters as well as the different lengths.
It is important to be able to correct an implant's choice during a procedure, to replace an implant which has been contaminated for any reason, to fit an extra implant in certain cases to insure the long term treatment sucess...
- We recommend the use of a safety system (floss attached to instruments or a suitable throat protection system) on the instruments in case of accidental dropping of tools in the patient's throat.

- It is strongly advised to put in place the receiving socket with **euroteknika groupe** instruments shown in this manual.

- The use of the implant requires a good mastery of the occlusion regulation, the management of implant axes during the preparation of the site, as well as a precise location of implants with regard to cusps and to occlusal forces. In a general way, any element of the treatment having an incidence on the distribution and the orientation of the masticatory constraints must be taken into account «not to overload» the implant.

- To use the OBI abutment implant in fixed prosthesis, it is necessary to study the available restorative space before the implant placement, and the feasibility of the insertion of the implant in the prosthetic axis.
This implant tolerates very few alterations (see chapter about the pre-implant study).

- When the OBI is used in removable prosthesis, the relining of the prosthesis is necessary to obtain a mucous support and not to concentrate the load on implants. A regular relining is necessary to assure the durability of the treatment.

PRE-IMPLANT STUDY

It is necessary to evaluate the possibility of an implantology treatment and to determine the treatment plan.

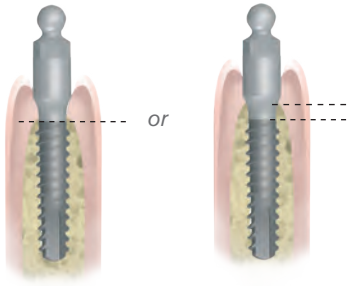
IMPLANT **treatment feasibility**

This study takes different elements into consideration

- A patient's questionnaire to reveal potential health/ medications problems which could have a bearing on the treatment success, alcohol, use tobacco or drugs, general dental hygiene...
- An oral examination which will give details about the mouth opening, the lign of the patient's smile (if it is a gingival smile), the coronary height and the volume of bone available, the type of occlusion...
- Biological tests (glycemy...)
- A complete X-Ray file showing the available bone's volumes
- Complete tests studies with the two dental arches in occlusion.
- An implant treatment cannot be started without a thourough cleaning of all the patient's infectious seats.

- The ball abutment implant used for the fixed prosthesis has an extra-osseous height of 8.5 mm.
- This height can be limited by burying a part of the implant neck (0.6 mm) see p.25.

- If it is necessary, in case of reduced coronal height in fixed prosthesis, the ball can be removed but only once the osseo-integration of the implant ended, that is under a period from 3 to 6 months according to the arch.

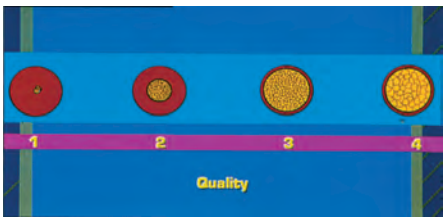


Maximum burying of the neck : 0.6 mm

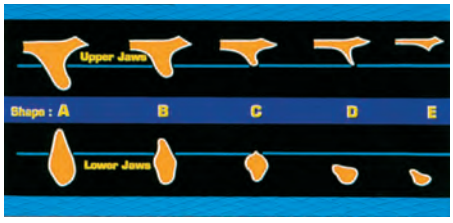
- In spite of the one-piece design of the implant, the immediate loading is not compulsory: possibility of leaving a prosthesis out of occlusion or, in case of removable prosthesis, not connecting ball abutments with the overdenture during the time necessary for the osseointegration.

However, because of the non-burying of the implant, and its small diameter, a precise analysis of the efforts applied to the implant and their distribution must be led to appreciate at best the feasibility of such a treatment.

The classification of osseous structures*



1 : very high density of compact bone
2 : thick layer of cortical bone around a dense core of spongious tissue
3 : thin layer of cortical bone around a big core of spongious tissue
4 : thin layer of cortical bone around a big core of low density of spongious tissue



A : important quality of remaining alveolar bone
B : limited resorption of the alveolar bone crest
C : important resorption of the alveolar bone crest
D : beginning of the basal resorption bone
E : important resorption of the basal bone

** Misch, (1998) Lekholm and Zarb (1985), Classification of partially edentulous arches for implant dentistry.*

Guide for the IMPLANTS CHOICE

Available bone volume

In the mesio-distal plan

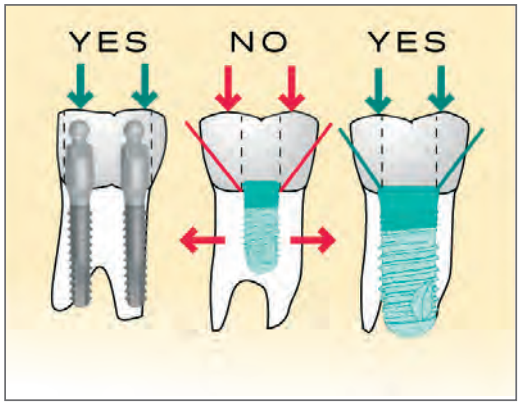
- Leave 2 mm between the implant's thread and natural teeth.
- Leave 3 mm between the thread of two implants.

In the labio-lingual palatal direction

Leave, if possible, 1.5 to 2 mm of bone thickness around the labial, palatal & lingual surfaces.

Dimensions of the crown and occlusal loads

- A precise analysis of the forces is essential to estimate the feasibility of the treatment with a small diameter implant.
- The supporting cusps must be situated in the implant axis (better distribution of the efforts to the bone).
- The implant must be placed in the center of the occlusal table and in the prosthetic axis.
- In the case of a removable prosthesis, the implants will have to be strictly parallel between them and situated perpendicularly to the occlusal plane.
- A regular relining of the prosthesis will allow to ensure the mucous support of the prosthesis and will so reduce the implants prompting.



Choice of the implant

- Only implants ref OIC.27.85.090, OIC.27.85.110, OIC.27.85.130, OIC.27.85.150 allow to realize fixed cement-retained prosthesis.
- These implants can also be used to stabilize a removable prosthesis in case of important gingival height.
- To stabilize a removable prosthesis, we recommend to use 4 implants, or at least 2. Select implants with a length of at least 11 mm if possible.

Use OF THE SURGICAL TRANSPARENCIES

In order to guide the choice of the implant in terms of length and diameter, **euroteknika goupe** has developed surgical transparencies that show the dimensions of its different implants. Thereby, the implants are represented with 1:1, 1.3:1 and 1.7:1 magnifications (magnifications correspond to the usual magnifications of the different types of medical imaging systems: retroalveolar X-ray, X-ray dental panoramic and tomography analysis SCANORA, CBCT (Cone Beam).

When the practitioner accurately knows the magnification of the pre-surgical X-ray, and if this magnification is 1:1, 1.3:1 or 1.7:1, by a simple superposition of the corresponding template (1:1 template for a 1:1 magnification, 1.3:1 template for a 1.3:1 magnification and 1.7:1 template for a 1.7:1 magnification), it is possible to determine which type of implant can be placed in the available bone volume.

When the practitioner does not know the magnification of the X-ray or to avoid any mistakes, he may place a reference object with known dimensions in the mouth of the patient when performing the X-ray examination in order to determine the associated magnification :

$$\textit{Magnification} = \frac{\textit{dimensions of the reference object measured on the radiograph}}{\textit{real dimensions of the reference object}}$$

The real dimensions of the reference object shall be known to a minimum accuracy of ± 15µm. The reference object shall be held in position using wax for example or by embedding the object in a partial impression. Care should be taken for the patient not to swallow the reference object. Use a safety thread if the geometry of the reference object allows it.

Then, if the calculated magnification is 1:1, 1.3:1 or 1.7:1, you may use the transparencies.

In all cases, if the magnification is not 1:1, 1.3:1 ou 1.7:1, it is not possible to use the transparencies provided by the **euroteknika goupe** but the bone volume may be determined thanks to proportionality calculation using the X-ray and the mesured magnification.

In this pre-implantation phase the practitioner must also design the coming prosthetic construction since implantology must be concidered as a prostheticaly driven project. Indeed, pre-prosthetic planning and surgical planning are closely linked and any change to one will have consequence on the other. It is during this phase that we may determine the number of implants, their diameters, their lengths, their locations and their orientations in order that we may proceed with the planned prosthetic construction.

SURGERY

Surgical KIT

The stake for the realization of the implant socket is on three levels :

- a calibration of the socket to obtain a good primary stability of the implant, main condition for the osteointegration.
- minimum **overheating** to avoid all irreversible bone necrosis. The socket preparation will be made under constant external irrigation with sodium chloride at 0.9%. The critical temperature threshold is 47°C for 1mn. At 50°C the necrosis is irreversible.
- the obtainment of a calibrated socket assuring a good imperviousness.
- The drilling axis should be controlled to avoid any angle between the prosthesis and the implant.

Use the drill guide in the gingival cutter to respect a constant working axis.

- The instruments are sorted by their stage of use as shown by a marked on the kit. Numbers notify the main steps of each stage.

BE CAREFUL

It is necessary to choose the prosthetic parts before the implant placement in order to insert the implant at the right place.

WARNING

The minimum heating will be achieved with a good irrigation and with a good selection of drills with a good cutting power. It is therefore necessary to check the number of use of the drills involved in the implant socket preparation.
Use the cursors in the surgical kit and change your drills after 10 to 15 uses.

Ref. OICK 27 XX 00

1. *Gingival cutter*
2. *Point drill Ø 1.5- Ø 2.2*
3. *Drill Ø 2*
4. *Depth Gauge*
5. *Paralleling pins*

- Click wrench

- Internal hexagonal screwdriver Ø 2.5 for the implant driving

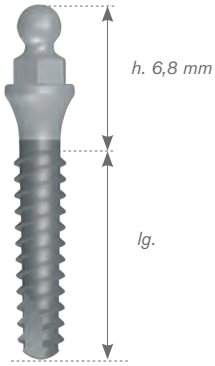
- Mandrel Extension

- Internal hexagonal mandrel Ø 2.5 for the implant driving (long and short)

Pictures for illustration purposes only

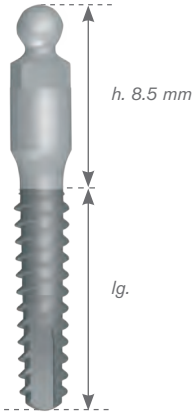
Mini implant range abutment/ball & ball OBI

Implants Ø 2.7 for removable prosthesis



- *Supplied on demand with an O'Ring attachement.*

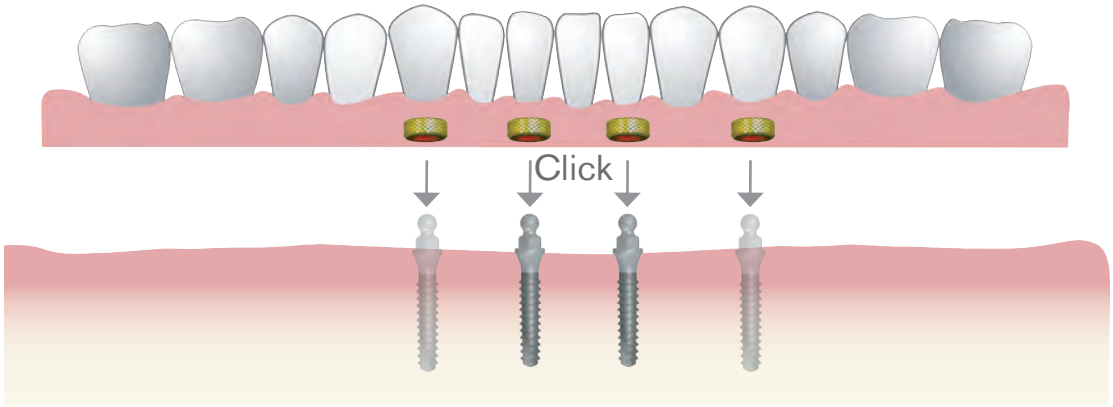
Implants Ø 2,7



- *Supplied on demand with a prosthetic part or an attachement.*
- *For cementer or removable prosthesis in case of important gingival thickness.*

A reliable solution for OVERDENTURE STABILIZATION

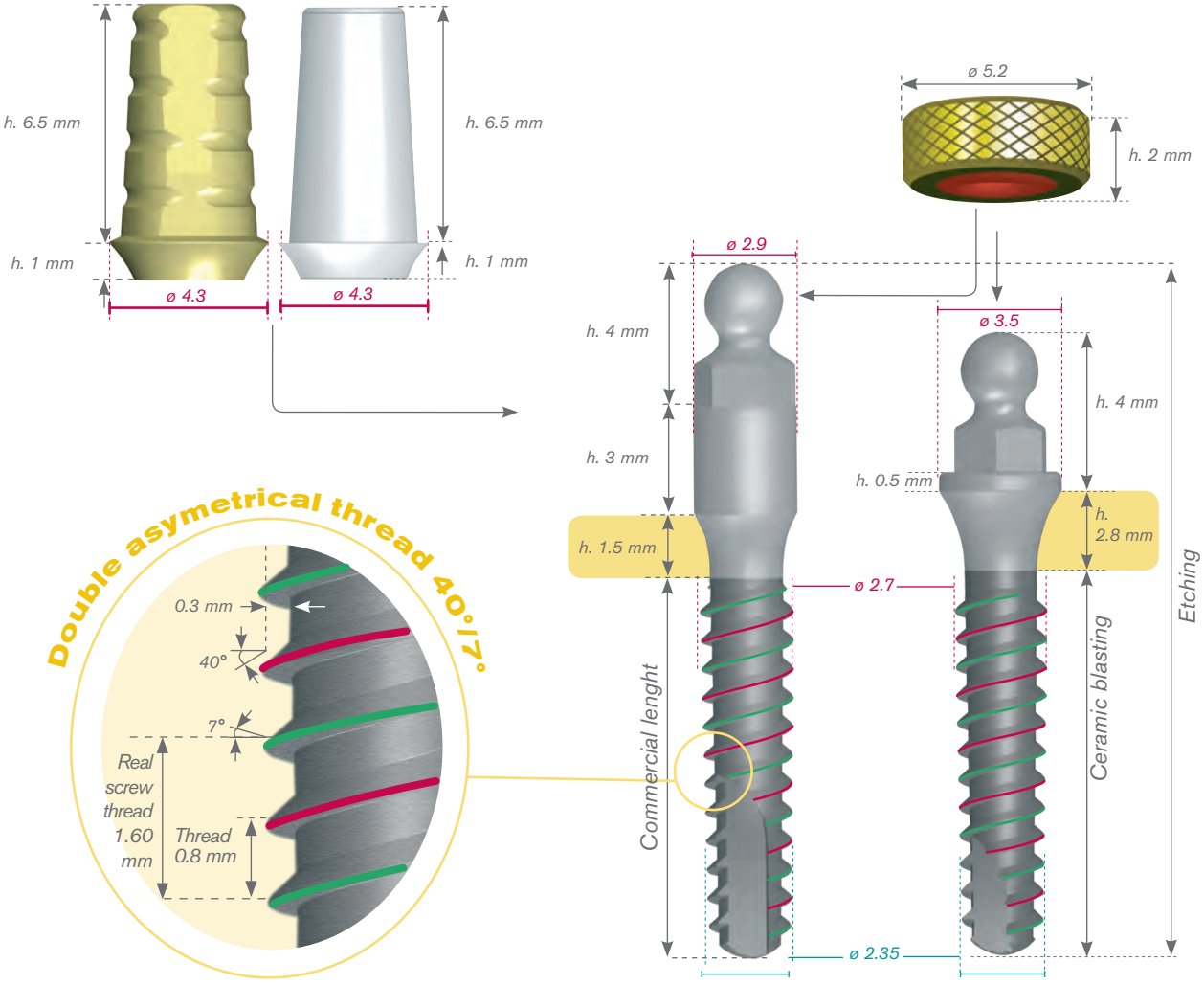
For thin edentulous crest, as an economical solution for some patients or for patients who do not accept implant treatment that requires several surgeries.

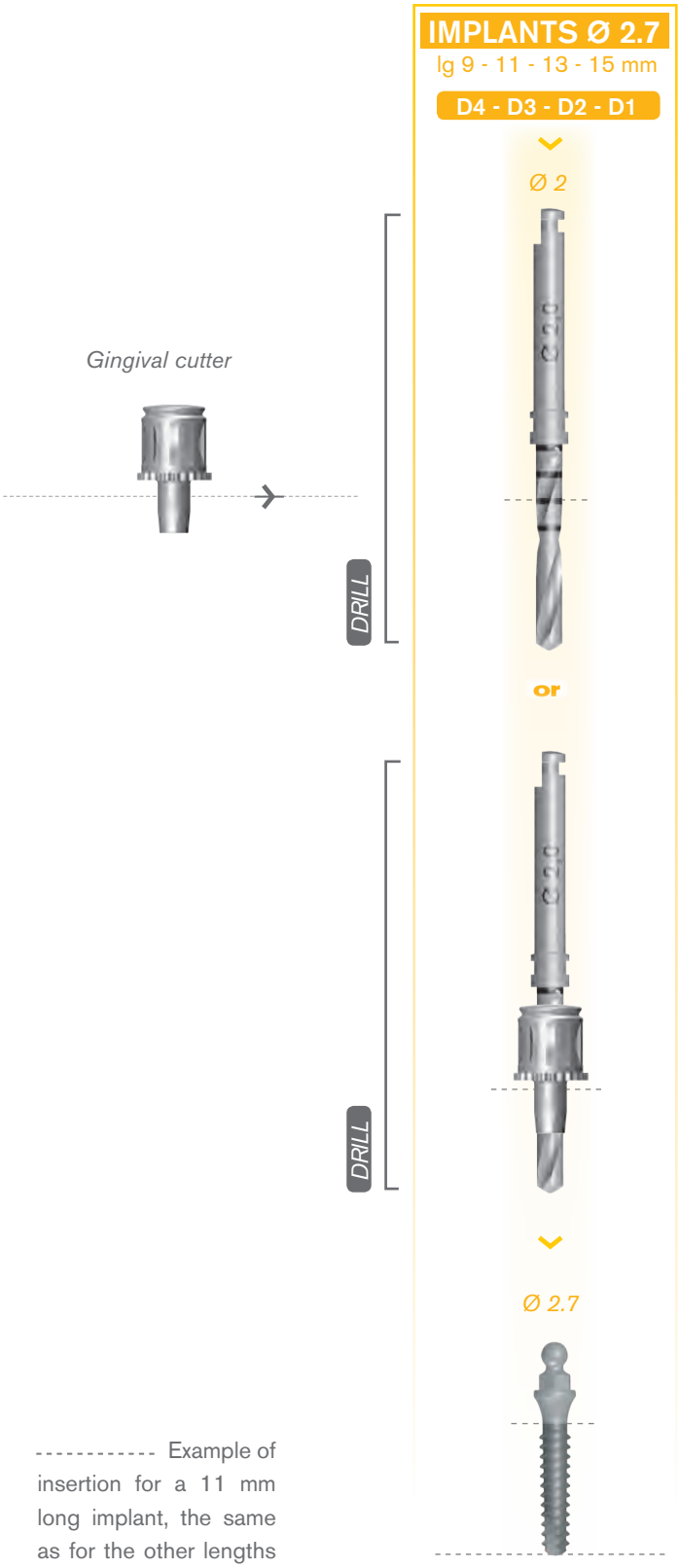


Minimal spacing CASES

The implant is well suited when Naturex Ø 3-2.2 implant is too large for the available bone space.

Implants PICTURES





Gingival cutter to guide the drill OPTIONAL

---------- Example of insertion for a 11 mm long implant, the same as for the other lengths of implants.

1 Incision

According to the available osseous volume and to the practitioner experience, the incision will be practised.

Either with a blade of scalpal:

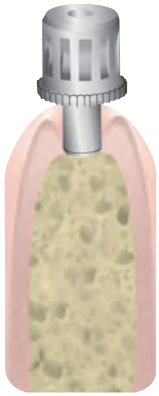
Make a crestal incision through the attached jaw, and then lift a flap.

Either with a gingival cutter supplied in the surgical kit:

Center the gingival cutter on the site to be implanted and press; remove the gingival piece in the center of the gingival cutter, put back the punch in place by checking its angular orientation because it will determine the drilling axis.

BE CAREFUL

Save a minimum space around the implants according to the rules of implantology.
In the labio-lingual / or palatal direction save 1.5 mm to 2 mm of bone.
In the mesio-distal plan, save 2 mm between a natural tooth & the implant thread, or 3 mm between 2 implants threads.

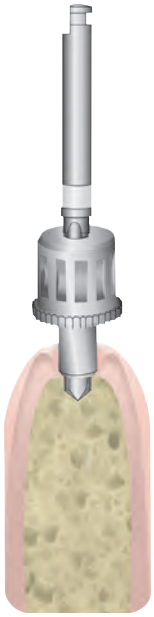


2 Drill diameter 2 MM

If the incision was carried by means of the gingival punch, the drill Ø 2 mm will be inserted into the central hole of the punch which will be used as a guide and will allow to stabilize the working axis of the drill at the time of the site shaping. It will then be correctly dimensioned. Check that the axis given by the mandrel of the drill is satisfactory before starting the motor.

Remove the punch after having made a first hole 3 or 4 mm deep.

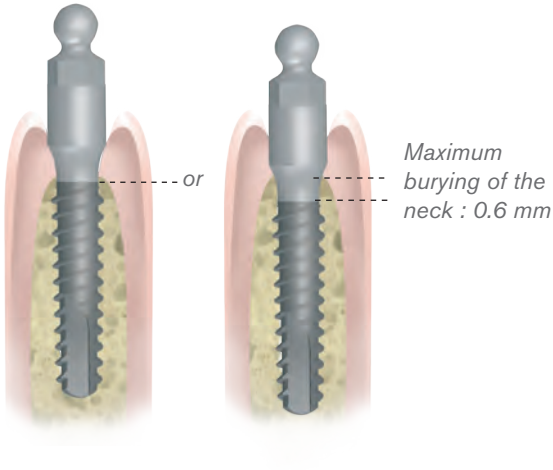
The implants lengths 9, 11, 13 and 15 mm correspond to the threaded and sandblasted lengths, but do not include the collar which will be placed over the crest. (p.21)



Finalize the drilling up to the determined mark on the drill, under constant external irrigation of sodium chloride, and at a speed ranging from 1000 to 1200 rpm according to the quality of the bone. The progress of the drill has to be made without forcing. If that was the case, it indicates that osseous fragments do not manage to evacuate by going back up along the helix. A simple up-and-down movement will allow to obtain a fluids progress of the drill. Be careful to work according to a constant axis. This movement does not require reverse motion of the motor direction if it is made at the right time. If the drill is blocked, it can be removed in «reverse» mode.

The depth of use of the drill is going to determine the implant compression in the bone. The drill Ø 2 mm is provided with 4 marks at 9, 11, 13 and 15 mm. These lengths are «point of drill included».

The peri-implant bone in the apical area of the implant is generally not so hard; the primary stability of the implant can be improved in this area by reducing the depth of drilling with regard to the total length of the implant. The implant is slightly conical and has self-tapping vents, so it can progress in this area.



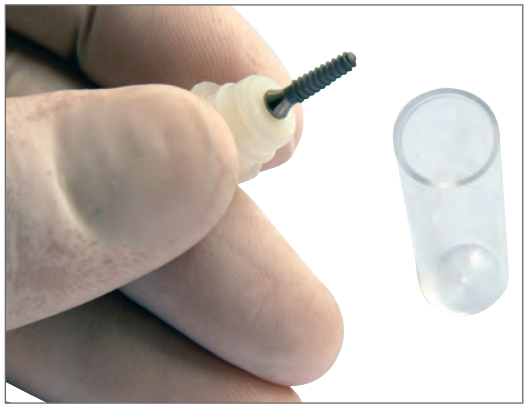
You can third bury the bottom of the collar (0.6 mm) without preliminary instrumentation to limit the overtaking over-crestal of the implant.

3 **Control** OF THE SOCKET AXIS

Insert the thinnest side of the parallelism gauge in the implant socket to evaluate the emergence axis of the implant and to guide the second drilling if necessary.

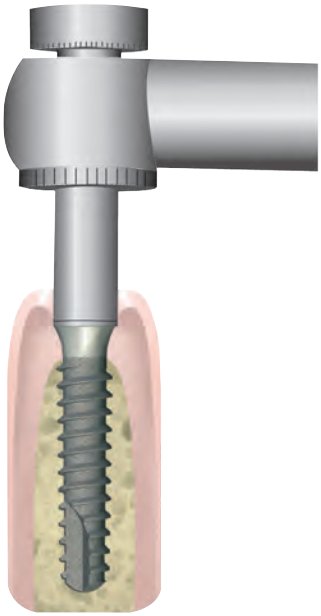
The top part of the gauge is necked to prefigure the implant neck (prosthetic support), and to save the necessary space between two implants.

4 **Implant** INSERTION



The implant can be positioned manually or with the contra-angle. This procedure must be done with the greatest care so that the implant does not come in contact with any non sterile element before insertion in the bone site. The cap of the implant tube can be used as an implant carrier. Take the implant to the implant bed, and insert it at the entrance of the well. Screw some turns of threading. Remove the cap and finish the screwing with the click-wrench provided with the internal hexagonal key.

For a good positioning in with the contra-angle, we recommend a speed of 15 to 25 rpm to control the descent of the implant. The positioning with the contra-angle allows to measure the insertion torque of the implant and to evaluate its primary stability. We recommend to set the implant at minimum 30 N.cm for a delayed loading, and higher than 40 N.cm for early or immediate loading.



It is recommended to check the primary stability of the implant at the end of the screwing by trying to move it. If the implant is loose , its primary stability is insufficient and will compromise the osseointegration; it is better to remove it and to use an implant with a greater diameter if the bone volume allows it.

5 **Osseointegration**

The conventional period to get a good osseointegration is 3 months at the mandibular.
The dentist must define this period by taking into account the bone quality, the implant primary stability and the prosthetic plan.
In certain cases, the dentist can decide to connect the prosthetic parts without waiting for the osseointegration. However, the dentist must be able to analyze if the conditions of the clinical case are appropriate to an immediate loading.
Studies and scientific datas indicate that immediate loading has proven to be successful at the mandibular when the prosthesis is built on 4 implants or more linked together. Immediate loading is not recommended on single implant.

⚠ **In case of failure**

To remove an implant, use a trephine with a greater diameter than the implant and remove the obtained bone cylinder.
The site can possibly be re-implanted, if the patient is fit to receive a new implant, with an implant of greater diameter, in the case that the placement of this implant occurs at the same time*.

To put another implant with a smaller diameter, it is better to wait for the complete healing of the socket **.

** It is important that the reasons of the failure should be analyzed before placing a new implant.*
*** The doctor decides if it is necessary to use some bone to fill in the socket.*

THE PROSTHESIS

1. Seat the titanium abutment on the coronary part of the implant; the titanium abutment is provided with grooves to be able to use it as an impression coping.

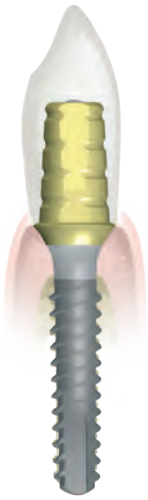
2. Making of the impression :
> On the ball of the implant with an elastic impression material. In this case, withdraw the impression and insert the analog of the ball abutment directly in the impression intray.
> On the titanium abutment, withdraw the impression and place the ball implant analog in the abutment and then in the impression intray.

3. Remove the impression.
At this stage, a temporary tooth can be made to protect the implant and to propose a temporary aesthetic solution (the temporary tooth is left out of occlusion in order not to damage osteo-integration).

4. Casting of the model.

NOTE

Only implants OIC 27 85 090, OIC 27 85 110, OIC 27 85 130, and OIC 27 85 150 allowed for this application.



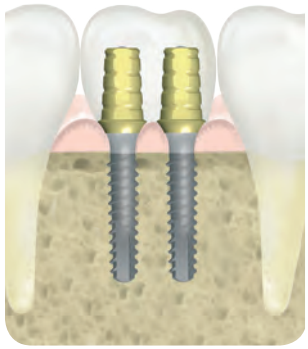
A Use of the TITANIUM ABUTMENT

5.a Seat the titanium abutment on the analog head in the model; in a conventional way, the plane will be presented on the palatal side. The titanium abutment has been designed to be as small as possible and cannot be cut.
If alterations are necessary, we recommend you to use the burn-out abutment (see b/).
6.a Put one or two coats of separator
7.a Model the wax model
8.a Casting
9.a The ceramic part is shaped, fired, and tried on the model
10.a Cement the titanium abutment on the implant, then cement the prosthesis on the titanium abutment.

⚠ The titanium abutments can not be modified or cut.
If a vertical reduction turns out necessary, get rid of the ball on the implant having wait for the necessary time for the osseointegration and use a burn-out abutment.

B Use of the BURN-OUT ABUTMENT

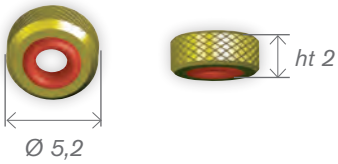
5.b Seat the burn-out abutment on the analog head taken in the model; its outline can be modified as often as you wish by the process of added wax. The line of gingival finish can so be customized, and answer many clinical situations, particularly when the festoon is curved and irregular.
6.b Modelling of the wax model.
7.b Casting.
8.b The ceramic part is shaped, fired, and tried out on the model.
9.b Cement the prosthesis on the implant head.

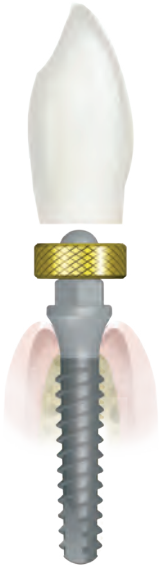


Overdenture STABILIZATION

BE CAREFUL

For the mandibile only. Be careful to have a mucous support of the prosthesis not to concentrate all the support and retention on the implants.





O'ring attachement
Ref. UPA FOR 52
O'ring attachement are supplied with 3 different retaining rings (50, 60 et 70 shores)

A If the removable prosthesis of the patient is re-used

The inner side of the removable prosthesis is hollowed out to place the female parts of all implant

1.A After the implant head is protected with a fine paper or insulating material, the female part is snapped on the implant head; some resin is introduced into the prosthesis, which is then seating in mouth by adjusting the occlusion and the positioning. The resin will get harder by autopolymerization.
2.A After the hardening of the resin around the female attachments, the prosthesis is ready.
3.A Reline the prosthesis to adjust the mucous support.

B If the prosthesis is made in the laboratory

1.B Make the impression on the titanium implants.
2.B Withdraw the impression.
3.B Insert the implant analogs in the impression.
4.B Cast the model.
5.B Snap the female parts.
6.B The prosthesis is made by means of teeth in resin positioned in the wax according to the same process as a complete prosthesis in exclusively mucous support.
7.B The prosthesis is placed on the articulator to check the occlusion and the positioning of teeth; adjustments if necessary.
8.B Put in the casting flask.
9.B Try the prosthesis on the model.
10.B Snap the prosthesis on the implants in the mouth.

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Implantologie orale 2003
Commission des dispositifs médicaux de l'ADF

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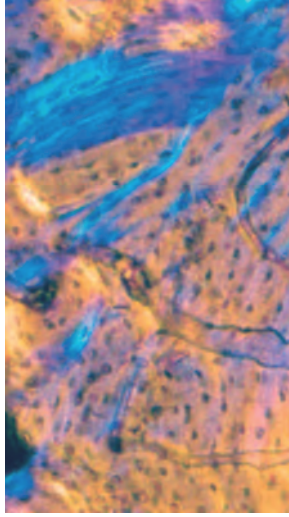
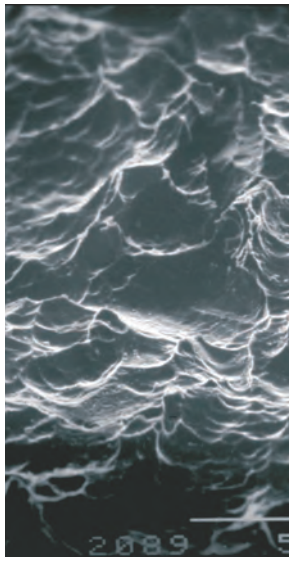
Franck Renouard





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